

Remarks/Arguments:

I. Status

The Office Action dated April 29, 2008 (the "Office Action") has been carefully reviewed. In the Office Action:

A. Claim 18 and the drawings were objected to;

B. Claims 1-7 and 8-14 were rejected as obvious over U.S. Patent Publication No. 2003/0216669 to Lang et al. (hereinafter "Lang") in view of U.S. Patent Publication No. 2003/0236473 to Dore et al. (hereinafter "Dore"); and

C. Claims 15 and 17-20 were rejected as obvious over U.S. Patent Publication No. 2002/0147455 to Carson et al. which issued as U.S. Patent No. 6,923,817 on August 2, 2005 (reference herein is made to U.S. Patent No. 6,923,817, hereinafter "Carson").

Claim 15 has been amended, claim 21 has been added, and claim 16 was previously canceled. Accordingly, claims 1-15 and 17-21 are pending consideration in this application. Reconsideration of this application, as amended, is respectfully requested.

II. The Objection to Claim 18 and the Drawings

The Examiner objected to claim 18 and the drawings for failure to show every feature of the invention specified in the claims. (Office Action at page 2). Reconsideration of the objection to claim 18 and the drawings is respectfully requested in view of the following remarks.

The Examiner correctly noted that 37 CFR 1.83(a) includes a requirement that a “drawing in a nonprovisional application must show every feature of the invention specified in the claims.” 37 CFR 1.83(a) further states, however, the following:

[C]onventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box).

The Applicant respectfully submits that articulating arms are known. By way of example, U.S. Patent No. 4,942,598 to Yuan et al. (hereinafter “Yuan”) describes a robotic arm that includes sensors to characterize the movement of the arm. (See, e.g., Yuan at Abstract). Accordingly, because an articulating arm is a conventional feature, even though it is recited in the claims, a proper understanding of the invention is achievable merely by a labeled rectangular box in the drawings.

FIG. 8 depicts a “reference pointer” 208 as a rectangular box. The reference pointer 208, in one embodiment, is “implemented with an articulating arm having positional gyros at each arm joint to provide positional data regarding movement of an articulating arm joint.” (Applicant’s specification at page 18, lines 11-14).

Therefore, because an articulating arm is a conventional feature, and because the reference pointer 208 is depicted in FIG. 8 as a labeled rectangular box, the Applicant submits that claim 18 and the drawings are in compliance with the requirements of 37 CFR 1.83(a) and the Examiner is respectfully requested to withdraw the objection to claim 18 and the drawings.

III. The Rejection of Claims 1-7 and 8-14 under 103(a)

Discussion Regarding Patentability of Claim 1

1. Claim 1

Claim 1 recites:

A method for designing a surgical guide for a joint replacement prosthesis comprising:
generating a bone surface image from three dimensional bone image data of a patient's bone;
generating a surgical guide image from the bone surface image and an image of a prosthetic implant imposed on the bone surface image; and
generating control data from the generated surgical guide image, the control data being used to control operation of a machine to fabricate a surgical guide.

Thus, claim 1 recites a method wherein a *surgical guide* is fabricated based upon

(i) an image of a bone surface, and (ii) an image of a prosthetic implant.

2. Prima Facie Obviousness Has Not Been Alleged

The Examiner rejected claim 1 based upon the proposition that Lang discloses the limitations of claim 1 with the exception of control data but that Dore discloses generation of control data. (Office Action at page 4). Respectfully, the Examiner has misconstrued the claim.

Specifically, the Examiner has alleged that the proposed combination results in the use of “image data to direct automatic construction of a prosthetic device.” (Office Action at page 2). As noted above, however, claim 1 is not directed to the fabrication of a “prosthetic device.” Rather, claim 1 is directed to the fabrication of a “surgical guide.” As used in the Applicant’s specification, a “surgical guide” refers to a device that is used to assist in preparation of a bone to receive a prosthetic device and/or placement of the prosthetic device. (See, e.g., Applicant’s specification at page 4, line 19 through the end

of page 5). Thus, a “surgical guide” is not the prosthetic device itself. The distinction between the surgical guide and the prosthetic device is further evidenced in the claim itself as the surgical guide is fabricated based upon an image of the prosthetic device.

Therefore, even if Lang is modified in the manner proposed by the Examiner, the proposed modification fails to arrive at the method recited in claim 1. Therefore, a *prima facie* case of obviousness has not been presented with respect to claim 1. Accordingly, the Examiner is respectfully requested to withdraw the rejection of claim 1.

2. Lang Does Not Disclose the Recited Method

The Applicant notes that Lang includes a discussion of the use of surgical tools at paragraphs 174 et seq. Therein, Lang discloses the use of “object coordinates that define the articular and/or bone surface and shape” with CAD/CAM techniques to adapt or select a device. (See, e.g., Lang at paragraph 175). Paragraphs 0176 and 0177 appear to describe what is meant by the language “adapt” and “select.” IN these paragraphs, Lang appears to disclose using the disclosed techniques to determine settings for devices (object coordinates are “entered or transferred into the device”, paragraph 0176) or the selection of the best fit from a library of devices (paragraph 0177).

Thus, Lang appears to disclose using controls provided on a device to adjust settings on that device for a particular patient. Lang does not, however, appear to disclose fabrication of a guide. Even if Lang could be construed as disclosing fabrication of a guide based upon an image of a bone surface, however, the Applicant has found nothing in Lang regarding the use of an image of a prosthetic device in addition to the use of a bone surface image to fabricate a guide.

Therefore, Lang, even when combined with Dore, fails to disclose fabrication of a *surgical guide* based upon (i) an image of a bone surface, and (ii) an image of a prosthetic implant as recited in claim 1.

3. Conclusion

Therefore, a *prima facie* case of obviousness has not been alleged with respect to claim 1. Moreover, none of the prior art cited by the Examiner discloses fabricating a *surgical guide* based upon (i) an image of a bone surface, and (ii) an image of a prosthetic implant as recited in claim 1. Accordingly, the Applicant submits that claim 1 is patentable over the cited art and the Examiner is respectfully requested to withdraw the rejection of claim 1.

Discussion Regarding Patentability of Claims 2-7

Claims 2-7 were rejected based upon the same combination discussed above with respect to claim 1. Claims 2-7 depend directly from independent claim 1 and include the limitations discussed above with respect to claim 1 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 1, it is respectfully submitted that the obviousness rejections of claims 2-7 based upon Lang in view of Dore should be withdrawn.

Discussion Regarding Patentability of Claim 8

Claim 8 was rejected based upon the same combination discussed above with respect to claim 1. Claim 8 recites:

A system for designing a surgical guide for a joint replacement prosthesis comprising:
a bone surface image generator for forming a bone surface image from three dimensional bone anatomical data for a patient's bone;
a surgical guide image generator for generating a surgical guide image from the bone surface image and an image of a prosthesis implant imposed on the bone surface image; and
a surgical guide image converter for generating control data to control operation of a machine for fabricating a surgical guide that corresponds to the surgical guide image.

Thus, claim 8 recites a system which fabricates a *surgical guide* based upon (i) an image of a bone surface, and (ii) an image of a prosthetic implant. For purposes of this rejection, this is the same limitation discussed above with respect to claim 1. Therefore, for at least the same reasons set forth above with respect claim 1, it is respectfully submitted that the obviousness rejection of claim 8 based upon Lang in view of Dore should be withdrawn.

Discussion Regarding Patentability of Claims 9-14

Claims 9-14 were rejected based upon the same combination discussed above with respect to claim 8. Claims 9-14 depend directly from independent claim 8 and include the limitations discussed above with respect to claim 8 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 8, it is respectfully submitted that the obviousness rejections of claims 9-14 based upon Lang in view of Dore should be withdrawn.

IV. The Rejection of Claims 15 and 17-20 under 103(a)

Discussion Regarding Patentability of Claim 15

1. Claim 15

Claim 15, as amended, recites:

A system for aiding a surgeon in a joint replacement operation comprising:
a patient bone data repository for storing three dimensional data of a patient's bone;
a reference pointer for providing positional data of a surgical site;
a registration module for (i) receiving the positional data, (ii) correlating the positional data for the surgical site obtained from the reference pointer to the three dimensional data for the bone stored in the patient bone repository, and (iii) determining changes in the surface of the bone using the received positional data; and
an image generator for generating an image of the patient's bone with an image of a prosthetic implant imposed on the image of the patient's bone.

Thus, claim 15 has been amended to recite a system which uses a reference pointer to generate data which is used to determine changes in the shape of bone as the bone is being shaped

2. Carson Does Not Disclose Determination of Changes

The Examiner rejected claim 15 based upon Carson. (Office Action at page 5). Claim 15 has been amended to recite limitations which more clearly distinguish over Carson.

Specifically, claim 15 has been amended to recite a registration module which determines the change in the form of a bone. As discussed at page 19, lines 11-16 of the Applicant's specification,

As bone is removed, the registration module 214 determines that the surface points of the volumetric data are changing. Consequently, the image presented by the image generator 218 changes to show the surgeon the changes to the implant site and what remains to be removed before the site is ready to receive the implant.

In contrast, Carson discloses the tracking of various mechanical axes (Carson at column 11, lines 25-31), prostheses (Carson at column 15, lines 14-16), guides (Carson at column 15, lines 55-60), and trials (Carson at column 16, lines 35-39). Carson does not, however, disclose a device for determining the changes in the surface of a bone.

3. Conclusion

Therefore, Carson does not disclose all of the limitations of claim 15, as amended. Accordingly, the Applicant respectfully submits that the rejection of claim 15 has been overcome and claim 15 is patentable over the cited art.

Discussion Regarding Patentability of Claims 17-20

Claims 17-20 were rejected based upon the same art discussed above with respect to claim 15. Claims 17-20 depend directly from independent claim 15 and include the limitations discussed above with respect to claim 15 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 15, it is respectfully submitted that the obviousness rejections of claims 17-20 based upon Carson should be withdrawn.

V. New Claim

Claim 21 has been added. Support for claim 21 may be found at page 19, lines 11-16 of the Applicant's specification. Claim 21 depends from claim 15. Accordingly, for at least the same reasons set forth regarding the patentability of claim 15, claim 21 is patentable over the prior art.

VI. Conclusion

Applicants respectfully request entry of the amendments and favorable consideration of the application.

A prompt and favorable action on the merits is requested.

Respectfully Submitted,
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/James D. Wood/

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